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Dated: **August 24, 2009**

Electronic Signature for Jill Gorny Sloper: /Jill Gorny Sloper/

Docket No.: CDJ-166CPRCE2
(PATENT)

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

In re Patent Application of:
Yashwant M. Deo *et al.*

Patent No.: 7,560,534
(USSN: 10/035,637)

Confirmation No.: 4452

Issued: July 14, 2009

Art Unit: 1644

For: MOLECULAR CONJUGATES COMPRISING
HUMAN MONOCLONAL ANTIBODIES TO
DENDRITIC CELLS (as amended)

Examiner: Ewoldt, Gerald R.

MS Patent Extension
Commissioner for Patents
P.O. Box 1450
Alexandria, VA 22313-1450

STATEMENT UNDER 37 CFR § 1.705(b)(2)

Dear Sir:

1. This statement is respectfully submitted in support of the “Application for Patent Term Adjustment Including Request for Reconsideration Under 37 CFR §1.705(b) and (d)” for the above-referenced patent. In view of the following, it is respectfully requested that Patentees be granted a minimum patent term adjustment of **582 days**.

2. The patent term adjustment as shown on the face of the issued patent is 171 days. A copy of the PTO’s Patent Term Adjustment calculation (“PTA Sheet”) available on Private Pair is also submitted herewith as Exhibit A. Patentees respectfully submit that the determination of 171 days of patent term adjustment is incorrect for the reasons discussed below.

3. The factual bases for the above adjustment are set forth as follows:

A. Examination Delays Pursuant to 37 CFR §1.702 and §1.703

Pursuant to 37 CFR §1.703(f), the period of adjustment of the term of the patent under §1.702 is the sum of the periods of examination delay calculated under subparagraphs (a)-(e), to the extent that such periods are not overlapping, less the sum of the periods calculated under §1.704 (the period of Patentee Delay). In the above-referenced application, Patentees are entitled to a period of examination delay equal to the sum of the periods of delay under §1.703(a) and (b) for the reasons set forth below.

(i) “14 Month Delay” Pursuant to §1.703(a)(1)

In accordance with 37 CFR §1.703(a)(1), Patentees are entitled to a period of patent term adjustment due to the failure by the Office to mail an action under 35 U.S.C. §132 not later than 14 months after the actual filing date (*i.e.*, by January 7, 2003). As shown in Exhibit A, the Office failed to mail an action under 35 U.S.C. §132 (a Restriction Requirement) until March 16, 2004. As such, Patentees are entitled to a period of patent term adjustment beginning January 8, 2003 and ending on March 16, 2004, the date of mailing of the Restriction Requirement by the Office. Accordingly, the period of patent term adjustment due to the 14 Month Delay by the Office is 434 days. This is consistent with the PTA Sheet (Exhibit A) from the Office.

(ii) “Three Years Delay” Pursuant to 37 CFR §1.703(b)

The Office did not comply with the requirement of 35 U.S.C. §154(b) and 37 CFR §1.702(b), which requires issuance of a patent within 3 years after the date on which the patent was filed under 35 U.S.C. §111(a). However, since the exclusionary period for continued examination set forth in 37 CFR §1.702(b)(1) applies to the instant patent, the number of days in the period beginning on the date on which Patentees first filed a Request for Continued Examination (March 30, 2006) and ending on the issue date of a corresponding patent (July 14, 2009), *i.e.*, 1203 days, is excluded from the period of Three Years Delay. Therefore, in accordance with 37 CFR §1.703, Patentees have calculated a maximum period of Three Years Delay based on the period of time beginning on the day after the date that is three years after the date on which the above-referenced patent was filed (*i.e.*, November 8, 2004), and ending on the date Patentees first filed a Request for Continued Examination (*i.e.*, March 30, 2006). This period of delay is 507 days.

Additionally, Patentees respectfully note that a Notice of Appeal was filed on January 30, 2006. Pursuant to 37 CFR 1.702(b)(4) the requirement that the Office must issue a patent within 3 years after the date on which the application was filed under 35 U.S.C. §111(a) does not include the period of appellate review by the BPAI or a Federal Court. However, as the Notice of Appeal that was filed on January 30, 2006 was effectively withdrawn by the subsequent Request for Reconsideration that was filed on March 30, 2006, the Exclusion for Appellate Review does not affect the present calculation.

(iii) “4 Month PTO Response to Patentee Reply” Pursuant to 37 CFR 1.702(a)(2)

Patentees respectfully submit that an additional period of examination delay of **113 days** accrued for the failure of the Office to issue a reply within four months, as required by 37 CFR 1.702(a)(2). Specifically, the Office did not respond to Patentees’ Response to Restriction Requirement (dated April 16, 2004) until December 7, 2004, *i.e.*, 113 days after a response was required under 37 CFR 1.702(a)(2).

Although the Office initially incorrectly calculated the examination delay under 37 CFR 1.702(a)(2) as beginning four months after Patentees’ Response to a Notice to Comply with Sequence Requirements (dated July 29, 2004), *i.e.*, a delay of 8 days, the Office has acknowledged this error in the Petition Decision dated June 9, 2009 (a copy of which is submitted herewith as Exhibit B). Specifically, the Office asserts that “a period [of] 113 days of adjustment, rather than a period of eight (8) days of adjustment, is warranted.” Accordingly, the Office has adjusted the PTA to correct this error, as shown in Exhibit A.

(iv) “4 Month PTO to Issue Patent” Pursuant to 37 CFR 1.702(a)(4)

Patentees respectfully submit that an additional period of examination delay of **110 days** accrued for the failure of the Office to issue a patent not later than four months after the date on which the issue fee was paid under 35 U.S.C 151 and all outstanding requirements were satisfied, as required by 37 CFR 1.702(a)(2). As shown in Exhibit A, the Office did not issue a patent until July 14, 2009. As such, Patentees are entitled to a period of patent term adjustment beginning March 27, 2009 and ending on July 14, 2009, the date the patent was issued by the Office. Accordingly, the period of patent term adjustment due to the 4 Month Delay by the Office is **110 days**. This is consistent with the PTA Sheet (Exhibit A) from the Office.

Calculation of Total Period of Examination Delay Pursuant to 37 CFR §1.703(f)

As set forth in 37 CFR §1.703(f), the period of examination delay based on the grounds set forth in 37 CFR §1.702 is the sum of the period of 14 Month Delay (434 days), the minimum period of Three Years Delay (507 days), the 4 Month PTO Response to Patentee Delay (113 days), and the 4 Month PTO Issue a Patent Delay (110 days) or 1164 days, to the extent these periods of delay are not overlapping. In this regard, Patentees respectfully submit that the only overlap that occurs is the period of the 4 Month PTO Response to Patentee Reply and the Three Year Delay overlap between November 7, 2004 through December 7, 2004, *i.e.*, by 30 days. Accordingly, the sum of the total examination delays (1164) is reduced by the period of overlap (30 days), resulting in a total examination delay of 1134 days.

B. “Patentee Delay” Pursuant to 37 CFR §1.704

Pursuant to 37 CFR §1.704 the period of adjustment of the term of the patent due to examination delay is reduced by the period of Patentee Delay. As shown in Exhibit A, the Office has calculated a period of Patentee Delay of 448 days. Patentees respectfully submit that the correct period of Patentee Delay is 552 days and seek correction based on the following remarks.

(i) Patentee Delay for Filing an Information Disclosure Statement

Patentees respectfully submit that an additional period of Patentee Delay of 104 days accrued for the delayed submission of an Information Disclosure Statement (IDS) on July 29, 2004. This IDS was filed without a statement under 37 CFR §1.704(d), 104 days after the filing of a response by Patentees to the Restriction Requirement on March 16, 2004. Pursuant to 37 CFR §1.704(c)(8), this 104 day period should be considered a Patentee Delay and should be added to the period of delay by Patentees.

Although the Office initially did not debit Patentees 104 days, the Office has acknowledged this error in the Petition Decision dated June 9, 2009 (Exhibit B). Specifically, the Office asserts that “entry of a period of reduction of 104 days is warranted.” Accordingly, the Office has adjusted the PTA to correct this error, as shown in Exhibit A.

(ii) Patentee Delay for Responding to Non-Final Action Dated December 7, 2004

Patentees respectfully submit that an additional period of Patentee Delay of **64 days** accrued for the delayed submission of an Amendment and Response on May 10, 2005. This is consistent with the PTA Sheet (Exhibit A) from the Office. Accordingly, pursuant to 37 CFR §1.704(b), this 64 day period should be considered an Patentee Delay and should be added to the period of delay by Patentees.

(iii) Patentee Delay for Responding to Final Action Dated July 29, 2005

Patentees respectfully submit that an additional period of Patentee Delay of **93 days** accrued for the delayed filing of a Notice of Appeal on January 30, 2006. This is consistent with the PTA Sheet (Exhibit A) from the Office. Accordingly, pursuant to 37 CFR §1.704(b), this 93 day period should be considered an Patentee Delay and should be added to the period of delay by Patentees.

(iv) Patentee Delay for Responding to Final Action Dated May 23, 2006

Patentees respectfully submit that an additional period of Patentee Delay of **91 days** accrued for the delayed submission of an Amendment and Response on November 22, 2006. This is consistent with the PTA Sheet (Exhibit A) from the Office. Accordingly, pursuant to 37 CFR §1.704(b), this 91 day period should be considered an Patentee Delay and should be added to the period of delay by Patentees.

(v) Reply Having Omission

Patentees respectfully submit that an additional period of Patentee Delay of **86 days** accrued for the submission of an Non-Responsive Amendment on November 22, 2006. This Non-Responsive Amendment is considered a “reply having an omission.” Therefore, pursuant to 37 CFR §1.704(c)(7), the period of adjustment shall be reduced by the number of days beginning on the day after the date the reply having an omission was filed (*i.e.*, November 23, 2006) and ending on the date that the reply correcting the omission was filed (*i.e.*, February 16, 2007), or 86 days. This is consistent with the PTA Sheet (Exhibit A) from the Office. Accordingly, this 86 day period should be considered an Patentee Delay and should be added to the period of delay by Patentees.

(vi) Patentee Delay for Responding to Final Action Dated May 9, 2007

Patentees respectfully submit that an additional period of Patentee Delay of **76 days** accrued for the delayed filing of a Request for Continued Examination on October 24, 2007. This is consistent with the PTA Sheet (Exhibit A) from the Office. Accordingly, pursuant to 37 CFR §1.704(b), this 76 day period should be considered an Patentee Delay and should be added to the period of delay by Patentees.

(vii) Patentee Delay for Filing an Information Disclosure Statement

Patentees respectfully submit that an additional period of Patentee Delay of **38 days** accrued for the delayed submission of an Information Disclosure Statement (IDS) on April 23, 2008, which was filed without a statement under 37 CFR §1.704(d). This is consistent with the PTA Sheet (Exhibit A) from the Office. Pursuant to 37 CFR §1.704(c)(8), this 38 day period should be considered an Patentee Delay and should be added to the period of delay by Patentees.

(viii) Calculation of the Total Period of Patentee Delay

In view of the above, Patentees have calculated a total period of Patentee Delay of **552 days** which is the sum of the following Patentee Delays: (i) the 104 day period; (ii) the 64 day period; (iii) the 93 day period; (iii) the 91 day period ; (iv) the 86 day period; (v) the 76 day period; and (vi) the 38 day period. Patentees respectfully submit that the correct period of Patentee Delay is **552 days**.

C. Calculation of Correct Patent Term Adjustment Pursuant to 37 CFR §1.702(f)

As set forth in 37 CFR §1.703(f), Patentees are entitled to a period of patent term adjustment equal to the period of examination delays reduced by the period of Patentee Delay. Therefore, Patentees submit that the correct patent term adjustment for the above-referenced patent is **582 days**, which is the difference between the total period of examination delay (1134 days) and the Patentee Delay (552 days).

4. In accordance with 37 CFR§1.705(b)(2)(iii), Patentees submit that the patent is subject to a terminal disclaimer over any patent issuing from U.S. Patent Application No.: 10/903191, entitled “Antibody Vaccine Conjugates and Uses Therefor.”

Dated: August 24, 2009

Respectfully submitted,

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